IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	:	Joel R. Studin
Serial No.	:	10/829,315
Filed	:	April 21, 2004
Examiner	:	Sheikh, Humera N.
Art Unit	:	1615
Title	:	*Method and Composition for the Treatment of Scars*

Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JOEL R. STUDIN UNDER 37 C.F.R. §1.132

I do hereby declare as follows:

1. THAT I received a Bachelor of Science in General Science and Psychology from the University of Rochester, Rochester, NY, in 1975.

2. THAT I received a Doctor of Medicine from Mount Sinai Hospital, New York, NY, in 1982.

3. THAT I have practiced as a Plastic and Reconstructive Surgeon since 1987.

4. THAT I am the inventor of the above-identified application, that I am familiar with the above-identified application, the Office Actions and applied references rendered to date.

5. Exhibit A is a testing report received from Bryce RX Laboratories, Inc., detailing the results of transdermal affect testing conducted by Bryce. I authorized Bryce RX Laboratories Inc. to undertake the transdermal affect testing. All dates and extraneous information have been redacted from Exhibit A.

6. Exhibit A reports the transdermal effectiveness evaluation of various possible carriers for delivering topical treatments including corticosteroids for scar tissue, psoriasis, eczema and other cutaneous maladies. Transdermal effectiveness was determined by the well-known McKenzie-Stoughton vasoconstriction assay. The McKenzie-Stoughton assay is a skin-blanching test. Under this assay a test sample containing a carrier and hydrocortisone was applied to a test subject's skin and the degree of skin blanching was observed. In accordance with the test, hydrocortisone

adsorbed into the skin causes a localized vasoconstriction at the site of application of the test sample. This vasoconstriction causes the skin to appear white. The more hydrocortisone that was adsorbed into the skin, the whiter the localized spot appeared. At 1, 2, and 4-hour time intervals an observer assessed the amount of skin blanching on a scale of 0 (least blanching) to 4 (most blanching). After all data had been collected from three different observers, the scores were added up to give a total blanching score. The higher the score, the higher the level of blanching, and thus, the higher the level of hydrocortisone adsorbed into the skin.

7. Exhibit A, page 1, provides further details for the preparation of the samples tested, and testing of those samples. Briefly, 50 ml of a carrier was added to a 200 ml beaker. 1 gm of hydrocortisone was added to the beaker and mixed until fully dissolved. Water was then added to a final volume of 100 ml. According to page 1, a 0.3 cc aliquot of each mixture was placed onto a subjects forearm and marked with a sharpie. Blanching was then observed at 1, 2, and 4-hour time intervals, and vasoconstriction was assessed on a scale of 0 (least blanching) to 4 (most blanching).

8. Exhibit A, pages 2-5, provides the blanching results from three observers at 1, 2, and 4-hour time intervals on four different test subjects for each carrier tested. Page 6 provides the cumulative score for each carrier tested for all four test subjects. As can be seen from page 6, Nitrocellulose (Flexible Collodion) had the highest test score (141), which indicates the greatest degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested.

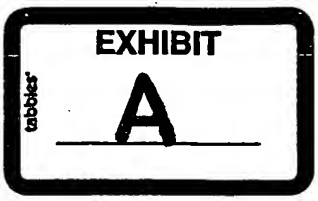
9. Exhibit A, page 6, also provides blanching results for methyl cellulose (14), hydroxymethylcellulose (25), nitrocellulose (flexible collodion/xanthan gum) (59), hydroxyethylcellulose (29), cellulose acetate (23), propylene glycol (7), aluminum hydroxide (49) and tragacanth (3). As can be clearly see from these results nitrocellulose showed very strong transmission of the active agent (hydrocortisone) into the test subject's skin.

10. I further declare that all statements made herein to my knowledge are true and that all statements made on information and belief are believed to be true: and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements so made may jeopardize the validity of the document, or application, or any patent issuing therefrom.

Respectfully submitted,

3/21/08
Date

Joel R. Studin



Formula: Scar/Ecz/Psoriasis Client: Dr. Joel Studin

TRANSDERMAL AFFECT TESTING
SCAR/ECZ/PSORIASIS - DR. STUDIN

The goal of this testing is to ascertain the relative efficacy of a number of possible carriers for delivering topical treatments including corticosteroids for scar tissue, psoriasis, eczema and other cutaneous maladies.

- - - - - -- - -- - - - - - - - METHOD / PROCESS- - - - - - - - - - - - - - - - - - - -

Transdermal effectiveness evaluation to be performed using the Coleman, Kanfer and Haigh method of the McKenzie - Stoughton vasoconstriction assay.

1. Place 50 ml of carrier into a 200ml beaker
2. Place 1gm hydrocortisone into beaker
3. Mix until fully dissolved or evenly dispersed
4. QS to 100ml
5. Seal beaker with plastic wrap
6. Repeat for all carriers.
7. Place 0.3cc aliquot of each mixture on flexor surface of subject forearm and mark with Sharpie
8. Subject to wear short sleeves and avoid washing or sweating
9. Observe at 1,2 and 4 hours
10. Chart observation of skin blanching by subject and 2 observers
11. Vasoconstriction assessed on a scale of zero=least blanching to 4=most blanching

SUBJECT #1

Base Carrier

Methyl Cellulose
Observation 1 _____ 1hr 1 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 0 4hr 0
Subject #1 _____ 1hr 0 2hr 0 4hr 0 Total Score 2

Hydroxymethylcellulose
Observation 1 _____ 1hr 1 2hr 1 4hr 1
Observation 2 _____ 1hr 1 2hr 1 4hr 0
Subject #1 _____ 1hr 0 2hr 0 4hr 0 Total Score 5

Nitrocellulose (Flexible Collodion)
Observation 1 _____ 1hr 4 2hr 4 4hr 4
Observation 2 _____ 1hr 4 2hr 4 4hr 4
Subject #1 _____ 1hr 3 2hr 4 4hr 4 Total Score 35

Nitrocellulose (Flexible Collodion / Xanthan Gum)
Observation 1 _____ 1hr 2 2hr 2 4hr 1
Observation 2 _____ 1hr 2 2hr 1 4hr 1
Subject #1 _____ 1hr 2 2hr 2 4hr 1 Total Score 14

Hydroxyethylcellulose
Observation 1 _____ 1hr 1 2hr 1 4hr 0
Observation 2 _____ 1hr 2 2hr 1 4hr 0
Subject #1 _____ 1hr 2 2hr 0 4hr 0 Total Score 7

Cellulose Acetate
Observation 1 _____ 1hr 1 2hr 1 4hr 0
Observation 2 _____ 1hr 1 2hr 0 4hr 0
Subject #3 _____ 1hr 0 2hr 0 4hr 0 Total Score 4

Propylene Glycol
Observation 1 _____ 1hr 1 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 0 4hr 0
Subject #1 _____ 1hr 0 2hr 0 4hr 0 Total Score 2

Aluminum Hydroxide
Observation 1 _____ 1hr 2 2hr 2 4hr 2
Observation 2 _____ 1hr 2 2hr 1 4hr 1
Subject #1 _____ 1hr 2 2hr 1 4hr 1 Total Score 14

Tragacanth
Observation 1 _____ 1hr 0 2hr 0 4hr 0
Observation 2 _____ 1hr 0 2hr 0 4hr 0
Subject #1 _____ 1hr 0 2hr 0 4hr 0 Total Score 0

SUBJECT #2

Base Carrier

Methyl Cellulose

Observation 1 1hr 1 2hr 1 4hr 1
Observation 2 1hr 2 2hr 1 4hr 0
Subject #2 1hr 1 2hr 0 4hr 0 Total Score 7

Hydroxymethylcellulose

Observation 1 1hr 2 2hr 1 4hr 1
Observation 2 1hr 1 2hr 0 4hr 0
Subject #2 1hr 1 2hr 0 4hr 0 Total Score 6

Nitrocellulose (Flexible Collodion)

Observation 1 1hr 4 2hr 4 4hr 4
Observation 2 1hr 4 2hr 4 4hr 4
Subject #2 1hr 4 2hr 4 4hr 3 Total Score 35

Nitrocellulose (Flexible Collodion / Xanthan Gum)

Observation 1 1hr 2 2hr 2 4hr 1
Observation 2 1hr 2 2hr 1 4hr 0
Subject #2 1hr 2 2hr 0 4hr 0 Total Score 10

Hydroxyethylcellulose

Observation 1 1hr 2 2hr 2 4hr 1
Observation 2 1hr 1 2hr 1 4hr 0
Subject #2 1hr 1 2hr 0 4hr 0 Total Score 8

Cellulose Acetate

Observation 1 1hr 1 2hr 0 4hr 0
Observation 2 1hr 1 2hr 1 4hr 0
Subject #2 1hr 1 2hr 0 4hr 0 Total Score 4

Propylene Glycol

Observation 1 1hr 1 2hr 0 4hr 0
Observation 2 1hr 1 2hr 0 4hr 0
Subject #2 1hr 0 2hr 0 4hr 0 Total Score 2

Aluminum Hydroxide

Observation 1 1hr 2 2hr 2 4hr 0
Observation 2 1hr 3 2hr 2 4hr 0
Subject #2 1hr 2 2hr 2 4hr 0 Total Score 13

Tragacanth

Observation 1 1hr 0 2hr 0 4hr 0
Observation 2 1hr 0 2hr 0 4hr 0
Subject #2 1hr 1 2hr 0 4hr 0 Total Score 1

SUBJECT #3

Base Carrier

Methyl Cellulose
Observation 1 _____ 1hr 1 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 1 4hr 0
Subject #3 _____ 1hr 0 2hr 0 4hr 0 Total Score 3

Hydroxymethylcellulose
Observation 1 _____ 1hr 1 2hr 1 4hr 1
Observation 2 _____ 1hr 1 2hr 1 4hr 1
Subject #3 _____ 1hr 1 2hr 0 4hr 0 Total Score 7

Nitrocellulose (Flexible Collodion)
Observation 1 _____ 1hr 4 2hr 4 4hr 4
Observation 2 _____ 1hr 4 2hr 4 4hr 4
Subject #3 _____ 1hr 4 2hr 4 4hr 4 Total Score 36

Nitrocellulose (Flexible Collodion / Xanthan Gum)
Observation 1 _____ 1hr 3 2hr 2 4hr 1
Observation 2 _____ 1hr 3 2hr 3 4hr 1
Subject #3 _____ 1hr 3 2hr 2 4hr 2 Total Score 20

Hydroxyethylcellulose
Observation 1 _____ 1hr 2 2hr 1 4hr 0
Observation 2 _____ 1hr 2 2hr 1 4hr 0
Subject #3 _____ 1hr 2 2hr 1 4hr 0 Total Score 9

Cellulose Acetate
Observation 1 _____ 1hr 2 2hr 1 4hr 0
Observation 2 _____ 1hr 2 2hr 1 4hr 0
Subject #3 _____ 1hr 1 2hr 0 4hr 0 Total Score 7

Propylene Glycol
Observation 1 _____ 1hr 1 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 1 4hr 0
Subject #3 _____ 1hr 1 2hr 0 4hr 0 Total Score 4

Aluminum Hydroxide
Observation 1 _____ 1hr 3 2hr 2 4hr 0
Observation 2 _____ 1hr 2 2hr 1 4hr 0
Subject #3 _____ 1hr 2 2hr 1 4hr 1 Total Score 11

Tragacanth
Observation 1 _____ 1hr 0 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 0 4hr 0
Subject #3 _____ 1hr 0 2hr 0 4hr 0 Total Score 1

SUBJECT #4

Base Carrier

Methyl Cellulose

Observation 1 _____ 1hr 0 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 0 4hr 0
Subject #4 _____ 1hr 1 2hr 0 4hr 0 Total Score 2

Hydroxymethylcellulose

Observation 1 _____ 1hr 2 2hr 2 4hr 1
Observation 2 _____ 1hr 1 2hr 1 4hr 1
Subject #4 _____ 1hr 0 2hr 0 4hr 0 Total Score 7

Nitrocellulose (Flexible Collodion)

Observation 1 _____ 1hr 4 2hr 4 4hr 4
Observation 2 _____ 1hr 4 2hr 4 4hr 4
Subject #4 _____ 1hr 3 2hr 4 4hr 4 Total Score 35

Nitrocellulose (Flexible Collodion / Xanthan Gum)

Observation 1 _____ 1hr 2 2hr 1 4hr 1
Observation 2 _____ 1hr 2 2hr 2 4hr 1
Subject #4 _____ 1hr 3 2hr 2 4hr 1 Total Score 15

Hydroxyethylcellulose

Observation 1 _____ 1hr 2 2hr 0 4hr 0
Observation 2 _____ 1hr 1 2hr 1 4hr 0
Subject #4 _____ 1hr 1 2hr 0 4hr 0 Total Score 5

Cellulose Acetate

Observation 1 _____ 1hr 1 2hr 1 4hr 0
Observation 2 _____ 1hr 1 2hr 1 4hr 1
Subject #3 _____ 1hr 1 2hr 1 4hr 1 Total Score 8

Propylene Glycol

Observation 1 _____ 1hr 0 2hr 0 4hr 0
Observation 2 _____ 1hr 0 2hr 0 4hr 0
Subject #4 _____ 1hr 1 2hr 0 4hr 0 Total Score 0

Aluminum Hydroxide

Observation 1 _____ 1hr 2 2hr 1 4hr 0
Observation 2 _____ 1hr 3 2hr 2 4hr 0
Subject #4 _____ 1hr 2 2hr 1 4hr 0 Total Score 11

Tragacanth

Observation 1 _____ 1hr 0 2hr 0 4hr 0
Observation 2 _____ 1hr 0 2hr 0 4hr 0
Subject #4 _____ 1hr 1 2hr 0 4hr 0 Total Score 1

BASE CARRIER CUMULATIVE TOTAL SUBJECTS 1-4 (1HR, 2HR, 4HR)

Methyl Cellulose
Subjects #1-4 Total Score 14

Hydroxymethylcellulose
Subjects #1-4 Total Score 25

Nitrocellulose (Flexible Collodion)
Subjects #1-4 Total Score 141

Nitrocellulose (Flexible Collodion / Xanthan Gum)
Subjects #1-4 Total Score 59

Hydroxyethylcellulose
Subjects #1-4 Total Score 29

Cellulose Acetate
Subjects #1-4 Total Score 23

Propylene Glycol
Subjects #1-4 Total Score 7

Aluminum Hydroxide
Subjects #1-4 Total Score 49

Tragacanth
Subjects #1-4 Total Score 3

Conclusion

Most carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation. We believe that this is a result of increased bio-electric binding. It is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.